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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,475

03/01/2004

Barry H. Ginsberg

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12/11/2007

ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.

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WASHINGTON,, DC 20036

EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

12/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/788,475	Applicant(s) GINSBERG, BARRY H.	
	Examiner PATRICIA C. MALLARI	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 10-19 and 28-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-27 and 41-62 is/are allowed.
- 6) ☒ Claim(s) 5.9 is/are rejected.
- 7) ☒ Claim(s) 6-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicant's amendments to the claims.

Response to Amendment

The response filed 9/27/07 has been received and entered.

Drawings

The objection to the drawings has been withdrawn in light of the applicant's amendment to the specification.

Oath/Declaration

The supplemental oath or declaration is defective. 37 CFR 1.67(a) states that a supplemental oath or declaration must meet the requirements of 37 CFR 1.62 or 1.63. See MPEP §§ 602.01, 602.02, and 603.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth above. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability"

(PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner.

Election/Restrictions

This application contains claims 1-4, 10-19, and 28-40 drawn to an invention nonelected with traverse in the reply filed on 4/9/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Application No. 2003/0028089 to Galley et al. in view of US Patent Application Publication NO. 2003/0055570 to Ribeiro et al. Galley discloses an apparatus for determining factor for insulin therapy, the apparatus comprising a memory device

storing at least one data set, wherein the data set comprises blood glucose readings for the beginning and end of a selected period of time, a value corresponding to patient's food intake for the selected period, and the amount of insulin administered during the selected period (see entire document, especially paragraphs 27, 35 of Galley). A processing device 14 is programmed to use an insulin sensitivity factor for the patient, wherein the initial insulin sensitivity factor is an estimated insulin sensitivity factor, the most recently known insulin sensitivity factor, and an initial insulin sensitivity factor (see entire document, especially paragraphs 32, 46, and 58 of Galley). While Galley does disclose a carbohydrate to insulin ratio (see entire document, especially paragraphs 61, 63-69, 77 of Galley), the reference lacks the processing device determining a carbohydrate to insulin ratio for the at least one data set using the insulin sensitivity factor.

Ribeiro et al. discloses determining a carbohydrate ratio being determined based on the insulin sensitivity (see entire document, especially paragraphs 45 and 52 of Ribeiro). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of determining the carbohydrate (or carbohydrate to insulin) ratio of Ribeiro in the apparatus of Galley, since Galley discloses using a carbohydrate ratio and Ribeiro describes an appropriate method of determining such a ratio.

Regarding claim 9, the processing device is a personal computer, hand held computing device, blood glucose monitor, calculator, therapeutic device for managing a patient's blood glucose levels, a diagnostic device for managing a patient's blood

glucose levels, or an informational device used for managing a patient's blood glucose levels (see entire document, especially paragraph 32 of Galley).

Response to Arguments

Applicant's arguments with respect to claims 5 and 9 have been considered but are moot in view of the new ground(s) of rejection.

In the remarks filed 9/27/07, the applicant stated that Galley et al, which is relied upon in the new grounds of rejection set forth above, fails to teach or suggest "the claim 5 recitations of storing a data set as claimed and the programmed processing device operations as claimed". However Galley clearly teaches the memory storing a data set, as explained in the rejection set forth above. Furthermore, Galley, as modified, by Ribeiro teaches the processor being programmed to operate as claimed, as also explained in the rejection set forth above.

The applicant also requested that if "the Examiner does not allow the application and continues to reject the claims over Galley et al", the "next office action be non-final since the Examiner did not state how Galley et al teaches most of the limitations of the claims". The application is not being allowed, and the claims are now rejected over Galley in view of Ribeiro, rather than as being anticipated by Galley. Additionally, the Examiner did indeed state in the previous Office action how Galley et al teaches most of the limitations of the claims and, contrary to the applicant's allegations, did not neglect to give proper patentable weight to the claim language. The Examiner properly treated the language "a memory device for storing at least one data set" in its broadest

reasonable interpretation recognizing that a memory *for* storing a data set and a memory *storing* a data set are two different things. Similarly, the Examiner properly treated the language, "a processing device programmable" in its broadest reasonable interpretation, also recognizing that a processing device *programmable*, or capable of being programmed to do something, is different from a processing device *programmed* to do something.

The applicant, himself, changed their claim language from "a memory device for storing at least one data set" to "a memory device storing at least one data set" and from "a processing device programmable" to "a processing device programmed". Clearly, that the applicant made such changes and did so in order to "more affirmatively" recite his invention is an indication that the applicant also recognized some difference in meaning between "programmable" and "programmed" and between "a memory device for storing" and "a memory device storing".

Because the previous Office action properly treated all the claims as written, and because the new grounds of rejection presented above were necessitated by the applicant's amendments to the claims, it is appropriate to make this Office action final.

Allowable Subject Matter

Claims 6-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20-27 and 41-62 are allowed. The allowability of claims 41-52 was addressed in the previous Office action, filed 6/27/07, and is repeated below.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 6, the primary reason for allowance is the inclusion of the processing device programmed to determine a weighted average for a carbohydrate to insulin ratio for a selected time period using the carbohydrate to insulin ratio for each of respective data sets, in combination with all of the other limitations of the claim, which is not found in the prior art.

Regarding claims 7 and 8, the primary reason for allowance is the inclusion of the combination of the processing device programmed both to determine a carbohydrate to insulin ratio for the at least one data set using the insulin sensitivity factor and to determine an insulin sensitivity factor for each data set using a carbohydrate to insulin ratio, in combination with all of the other limitations of the claim, which is not found in the prior art.

Regarding claims 20-27, the primary reason for allowance is the inclusion of the processing device programmed to calculate a delta blood glucose level corresponding to the difference between the blood glucose readings taken, respectively, at substantially the beginning of and substantially the end of the selected period and determining a correct insulin amount using the delta blood glucose level, insulin sensitivity factor, and amount of insulin administered to the patient during the selected

period, in combination with all of the other limitations of the claims, which is not found in the prior art.

The primary reason for the allowance of claims 41-51 is the inclusion of combination of the second set of instructions to calculate a delta blood glucose level corresponding to the difference between readings taken respectively, at substantially the beginning of and substantially the end of the selected period and the third set of instructions to determine a correct insulin amount using the delta blood glucose level divided by an insulin sensitivity factor.

Regarding claims 52-62, the primary reason for allowance is the inclusion of the processing device programmed to calculate a delta blood glucose level corresponding to the difference between the blood glucose readings taken, respectively, at substantially the beginning of and substantially the end of the selected period and determining a correct insulin amount using the delta blood glucose level divided by an insulin sensitivity factor, in combination with all of the other limitations of the claims, which is not found in the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/P. C. M./
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